



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0357; FRL-9373-9]

Fenpyrazamine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpyrazamine in or on multiple commodities which are identified and discussed later in this document.

Valent U.S.A. Corporation and Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0357, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Gene Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-0235; email address: *benbow.gene@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the

instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0357 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0357, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 6, 2011 (76 FR 39358) (FRL-8875-6) and of July 20, 2011 (76 FR 43233) (FRL-8880-1), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 1F7841) by Valent U.S.A. Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596 and PP 1E7850 by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide fenpyrazamine, S-allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3-dihydropyrazole-1-carbothioate, in or on: Almond at 0.02 parts per million (ppm); almond, hulls at 1.5 ppm; lettuce, head at 2.5 ppm; lettuce, leaf at 2.5 ppm; small fruit vine climbing subgroup, except fuzzy kiwi fruit, crop subgroup 13-07F at 3.5 ppm; grape, juice at 7.0 ppm; grape, raisins at 4.5 ppm; low growing berry subgroup 13-07G at 3.0 ppm (PP 1F7841); pistachio at 0.02 ppm; Caneberry subgroup 13-07A at 7.0 ppm; Bushberry subgroup 13-07B at 7.0 ppm; and ginseng at 0.80 ppm (PP 1E7850). Those documents referenced a summary of the petitions prepared by Valent U.S.A. Corporation, the registrant, which are available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notices of filing.

Based upon review of the data supporting the petition, EPA has determined that the tolerances should be based upon parent fenpyrazamine only, has revised the tolerance levels for several commodities, and determined a tolerance is not needed for raisins. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fenpyrazamine including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenpyrazamine follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The principal toxicological findings for fenpyrazamine in repeated dose studies in rodents, rabbits, and dogs were reduced bodyweights/ bodyweight weight gains. In addition, thyroid follicular cell hypertrophy was observed in rats in the subchronic, chronic/carcinogenicity and reproduction toxicity (parental animals only) studies. Although increased liver weights, hepatocellular hypertrophy, and alterations in hematology and clinical chemistry parameters were observed in several studies, they were not considered to be toxicologically relevant since the magnitude of the changes was within normal variability. The liver alterations were therefore considered adaptive rather than adverse effects.

There was no evidence of increased susceptibility of developing organisms after *in utero* or post-natal exposure to fenpyrazamine in the developmental toxicity studies (rats and rabbits) or the multi-generation reproduction toxicity study. In both the rat and rabbit developmental studies, maternal effects (decreased body weight) occurred at doses lower than or equal to those eliciting developmental effects (decreased fetal weight, skeletal variations in rats and late abortions and premature deliveries in rabbits). Since the late abortions and premature deliveries occurred at doses higher than the maternal LOAEL, this finding is not considered to be indicative of susceptibility. In the multi-generation reproduction toxicity study, thyroid toxicity was observed in parental animals at the same dose eliciting decreased body weights in the offspring. Reproductive effects manifested as decreases in implantations and increases in postimplantation loss occurred at a dose level approximately 4x higher than the parental and offspring LOAELs.

The only potential sign of neurotoxicity was a decrease in total motor activity and total number of rearings observed in the acute neurotoxicity study in rats. However,

given that the liver is the target tissue, these effects may be nonspecific effects secondary to general toxicity. These effects were not observed in the subchronic neurotoxicity or any other studies in the database.

In a 28-day dermal toxicity study, no hazard was identified at the limit dose 1,000 milligrams/kilogram/day (mg/kg/day). Similarly, an immunotoxicity study in rats did not indicate that the immune system is a target for fenpyrazamine toxicity.

Although an increase in the incidence of hepatocellular and thyroid follicular carcinomas was noted in the chronic/carcinogenicity study in rats, the concern for these findings is low based on the following weight of evidence considerations:

1. The marginal increases occurred only at the high dose;
2. There was no reduction in the latency period (i.e., tumors were seen only at the terminal sacrifice); and
3. The incidences were only slightly outside the historical control range of the testing laboratories.

In addition, no neoplastic lesions attributable to treatment were observed in the carcinogenicity study in mice and no indication of mutagenicity was noted in the mutagenicity battery. Based on this evidence, in accordance with the Agency's 2005 Guidelines for Cancer Risk Assessment, EPA classified fenpyrazamine as "Not Likely to be Carcinogenic to Humans".

Specific information on the studies received and the nature of the adverse effects caused by fenpyrazamine as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in section 4.5.4 in the document "Human Health Risk

Assessment for the Section 3 Registration and Establishment of Tolerances on Almond, Small Fruit Climbing Subgroup 13-07F, Head and Leaf Lettuce, and Low Growing Berry Subgroup 13-07G, Bushberry Subgroup 13-07B, Caneberry Subgroup 13-07A, Ginseng, and Pistachio” in docket ID number EPA-HQ-OPP-2011-0357.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fenpyrazamine used for human risk assessment is shown in the following Table.

Table --Summary of Toxicological Doses and Endpoints for Fenpyrazamine for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children and females 13-49 years of age)	NOAEL= 80 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.8 mg/kg/day aPAD = 0.8 mg/kg/day	Acute Neurotoxicity Screening Battery-Rats LOAEL = based on a statistically significant decrease in total motor activity (total distance) in males at 400 and 2,000 mg/kg/day on day 1. Number of rearings was statistically decreased in males at 400 and 2,000 mg/kg/day, and in females at 2,000 mg/kg/day on day 1.
Chronic dietary (All populations)	NOAEL= 30 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.3 mg/kg/day cPAD = 0.3 mg/kg/day	Developmental Toxicity Study in Rabbits Maternal LOAEL = 50 mg/kg/day [based on decreased body weight and food consumption].
Cancer (Oral, dermal, inhalation)	Fenpyrazamine is classified as "Not Likely to be Carcinogenic to Humans".		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. LOC = level of concern. N/A = not applicable.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenpyrazamine, EPA considered exposure under the petitioned-for tolerances in 40 CFR 180. EPA assessed dietary exposures from fenpyrazamine in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects

were identified for fenpyrazamine. In estimating acute dietary exposure, EPA used food consumption information from the 2003 to 2008 United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). For residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance level residues of parent fenpyrazamine plus the maximum residue of S-2188-DC (expressed as parent fenpyrazamine) observed in the crop field trials for the proposed uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003 to 2008 United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). For residue levels in food, EPA assumed 100 PCT and tolerance level residues of parent fenpyrazamine plus the maximum residue of S-2188-DC (expressed as parent fenpyrazamine) observed in the crop field trials for the proposed uses.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenpyrazamine does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for fenpyrazamine. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fenpyrazamine in drinking water. These simulation models take into account data on the physical,

chemical, and fate/transport characteristics of fenpyrazamine. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier 1 FQPA Index Reservoir Screening Tool (FIRST v. 1.1.1, released March 26, 2008) for surface water and the Screening Concentration in Ground Water (SCI-GROW) model for ground water, the estimated drinking water concentrations (EDWCs) of fenpyrazamine for acute exposures are estimated to be 213.5 parts per billion (ppb) for surface water and 1.31 ppb for ground water. The chronic exposures are estimated to be 72.5 ppb for surface water and 1.31 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 213.5 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 72.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fenpyrazamine is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have

a common mechanism of toxicity.” EPA has not found fenpyrazamine to share a common mechanism of toxicity with any other substances, and fenpyrazamine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenpyrazamine does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased pre- and/or postnatal susceptibility based on the results of the rat and rabbit prenatal developmental toxicity studies, and the rat 2-generation reproductive toxicity study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for fenpyrazamine is complete.

ii. There is no evidence of increased pre- and/or postnatal susceptibility for fenpyrazamine.

iii. There is no residual uncertainty in the exposure database for fenpyrazamine with respect to dietary (food and water) exposure. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues of parent fenpyrazamine plus the maximum residue of the metabolite S-2188-DC, empirical concentration factors and default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenpyrazamine in drinking water. These assessments will not underestimate the exposure and risks posed by fenpyrazamine.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and chronic population-adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists. Since there are no residential uses proposed for fenpyrazamine, the aggregate risks are equal to the dietary and drinking water assessments.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenpyrazamine will occupy 9.2% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenpyrazamine from food and water will utilize 7.3 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term or intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fenpyrazamine is not registered for any use patterns that would result in short-term or intermediate-term residential exposure. Short-term and intermediate-term risk is assessed based on short-term or intermediate-term residential exposure plus chronic dietary exposure. Because there is no short-term or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term and intermediate-term risk for fenpyrazamine.

4. *Aggregate cancer risk for U.S. population.* Based on the results of two adequate rodent carcinogenicity studies, fenpyrazamine is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fenpyrazamine residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Parent fenpyrazamine only is the residue of concern for tolerance enforcement purposes. Valent U.S.A. Corporation has submitted the results of an independent laboratory validation (ILV) by liquid chromatography and mass spectrometry (LC/MS/MS), Method RM-45C-1, titled “Determination of S-2188 and S-2188-DC in crops”. The method is considered adequate for enforcement of tolerances in plant commodities.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Fenpyrazamine is a new active ingredient and MRLs have not been established by Codex, Canada, or Mexico for the commodities proposed for registration in the US.

C. Revisions to Petitioned-For Tolerances

The Agency established parent fenpyrazamine only as the residue of concern for tolerance enforcement in plants and tolerances were recommended accordingly. These differ from the tolerances proposed by the registrant, which are based on residues of parent fenpyrazamine and the metabolite S-2188-DC expressed as fenpyrazamine. In addition, the Organization for the Economical Cooperation and Development (OECD) calculation procedures were used to estimate the tolerances and based on these procedures, the Agency has determined that the lettuce, head tolerance should be lowered from 2.0 to 1.5 ppm; lettuce, leaf from 2.5 ppm to 2 ppm; Caneberry subgroup 13-07A from 7.0 ppm to 5 ppm; Bushberry subgroup 13-07B from 7.0 ppm to 5 ppm; small fruit vine climbing subgroup except fuzzy kiwi fruit, subgroup 13-07F from 3.5 ppm to 3 ppm; and grape, juice from 7.0 ppm to 4 ppm. Finally, the submitted grape processing data indicate that residues of parent fenpyrazamine only concentrate in raisins at 1.1x. Therefore, the concentration factor for raisin is not high enough to justify the need of a separate tolerance for raisins.

V. Conclusion

Therefore, tolerances are established for residues of fenpyrazamine, S-allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3-dihydropyrazole-1-carbothioate, in or on Almond at 0.02 ppm; almond, hulls at 1.5 ppm; pistachio at 0.02 ppm; lettuce, head at 1.5 ppm; lettuce, leaf at 2 ppm; Caneberry subgroup 13-07A at 5 ppm; Bushberry subgroup 13-07B at 5 ppm; small fruit vine climbing subgroup except fuzzy kiwi fruit, subgroup 13-07F at 3 ppm; grape, juice at 4 ppm; low growing berry subgroup 13-07G at 3 ppm; and ginseng at 0.7 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on

the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 21, 2013.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In subpart C, add § 180.671 to read as follows:

§ 180.671 Fenpyrazamine; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide fenpyrazamine, in or on the following commodities. Compliance with the tolerance levels specified in the following table is to be determined by measuring only fenpyrazamine S-allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3-dihydropyrazole-1-carbothioate, in or on the following commodities:

Commodity	Parts per million
Almond	0.02
Almond, hulls	1.5
Berry, low growing, subgroup 13-07G	3
Bushberry subgroup 13-07B	5
Caneberry subgroup 13-07A	5
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	3
Ginseng	0.7
Grape, juice	4
Lettuce, head	1.5
Lettuce, leaf	2
Pistachio	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]